User Manual

Medical Isolator

MI 1005

Galvanic Ethernet Isolator
for medical electrical appliances
in accordance with

IEC/EN 60601-1 and IEC/EN 60601-1-2

Table of Contents

1. General Safety Advise

a. Before use the following section should be read carefully through to the end.
b. The **MI 1005** can only be installed and put into operation by qualified and trained personnel.
c. Do not open the housing; there are no serviceable parts inside. Faulty or defective devices have to be exchanged and returned to the manufacturer.
d. Before starting the MI 1005, ascertain without fail from the manufacturer of your medical appliances/systems whether they – with sufficient galvanic isolation – permit coupling to the local network (LAN) or to other computer.

1.1 Location

During installation ensure that the MI 1005 is protected from penetration by moisture, high humidity and mechanical damage. It should not be operated in close proximity to atmospheres with combustible composites.

The MI 1005 should also not be operated in close proximity to devices that emit electromagnetically radiation to avoid electromagnetically interferences like for example mobile phones. Potential interferences can be avoided by operating the MI 1005 outside this electromagnetically environment.

1.2 Connection

When connecting the **MI 1005** Medical Isolator please observe that:

a. you do not connect any telecommunications appliances, voltage supplies or similar to the **MI 1005**. By doing so, both the **MI 1005** and personnel could be harmed!
b. you only connect network components complying with IEEE 802.3 or IEEE 802.3ab (10/100/1000-BaseT, Twisted-Pair) to the MI 1005.
c. you use, without exception, tested and approved CAT 6 network cable (with appropriate test mark).

1.3 Environmental Protection

For disposal of the MI 1005 stipulations subject to public law may involve special instructions. Before the final de-commissioning of the appliance, contact the manufacturer.

1.4 Meaning of used symbols

Accompanying documents!

2. Intended Use

The **MI 1005** is an appliance especially developed for use in medical technology. The purpose of the **MI 1005** is to connect, in compliance with the relevant norms for electrical safety (IEC 60601-1) and EMC (IEC 60601-1-2), a medical appliance or system equipped with a network interface to a non-medical appliance or system (Single PC or local network).

Examples for the use of the **MI 1005** :

- Connection to the practice or clinic networks with the PC of a prolonged EEG system
- Connection to an analysis computer in the doctor's or consulting room with an EMG measuring station

Point d. of Chapter 1 - General Safety Advice - is to be observed for this.

3. Installation

Only qualified and trained personnel should connect the **MI 1005**. Please instruct your network systems administrator or your medicine technology department for this purpose. The installation of the **MI 1005** is done by means of the two pluggable connections (RJ-45-sockets). To do this, plug the network connection cable into the socket of the **MI 1005**, until the lock engages with an audible ‚click'. The installation of the **MI 1005** should be done near the medical appliance/system. The safety advice in Chapter 1.2 – Connection - is to be observed!

4. Maintenance

For maintaining a safe technical condition, an annual inspection is recommended, which includes the following checks:

1. Examination for external damage (housing, network connections, legibility of labeling, dirt, etc.) of the **MI 1005** .
2. Examination for substances which may have penetrated, in particular moisture.
3. Function test.
4. Isolation test. The isolation resistance of the MI 1005 should not exceed 20 MOhm. For testing, at both connections all data cables as well as the screen should always be shut down briefly. The isolation resistance should be measured between signal entry and signal exit.
5. Availability and sufficiency of the documents.

Should any deficiency be established during a test, the MI 1005 should not be used any longer, as the safety of the patients and the operator cannot be guaranteed.

In case of doubt please contact your supplier or the manufacturer.

5. Cleaning

Use a dry or a moderately moisturized cloth to clean the **MI 1005**. It must be noted that no fluids or moisture will penetrate into the device.

6. Declaration of Conformity

EG - Konformitätserklärung

EC declaration of conformity

Baaske Medical

Baaske Medical GmbH & Co. KG
Siemensstr. 5
32312 Lübbecke
Deutschland / Germany

erklärt in alleiniger Verantwortung, dass die Produkte
declares in sole responsibility, that the products

Typ: MI 1005
MI 1005 E

mit den grundlegenden Vorschriften der folgenden EG-Richtlinien übereinstimmt, wenn es für seinen bestimmungsgemäßen Zweck verwendet wird:
complies with the essential requirements of the following EC-Directives, if used for its intended use:

EMV-Richtlinie 2004/108/EG
EMC Directive 2004/108/EG

Niederspannungsrichtlinie 2006/95/EG
Low-Voltage Directive 2006/95/EEC

RoHS Richtlinie 2011/65/EU
RoHS Directive 2011/65/EU

Angewandte harmonisierte Normen oder normative Dokumente:
Applied harmonized standards or normative documents:

IEC 60601-1:2005 / EN 60601-1 : 2006
IEC 60601-1-2:2007 / EN 60601-1-2 : 2007
UL 60601-1 (e342310)

Lübbecke, 05.03.2013	Andreas Baaske (GF)	
Ort und Datum der Ausstellung *Place / Date*	Angaben zum Unterzeichner *Issuer*	Unterschrift *Signature*

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Richtlinien, beinhaltet jedoch keine Zusicherung von Eigenschaften. Die Sicherheitshinweise der mitgelieferten Produktdokumentation sind zu beachten.

This declaration certifies the conformity with the named directives, but does not contain any assurance of quality. The safety instructions of the instruction manual are to be followed.

Certificate of Compliance

Certificate Number 20110729-E342310
Report Reference E342310-A1-UL
Issue Date 2011 July 29

Underwriters Laboratories

Issued to: BAASKE MEDICAL GMBH & CO KG
SIEMENSSTRASSE 5
32312 LUEBBECKE GERMANY

This is to certify that representative samples of MEDICAL EQUIPMENT

Medical isolator - MI 1005, MI 1005 E

Have been investigated by Underwriters Laboratories in accordance with the Standard(s) indicated on this Certificate.

Standard(s) for Safety: UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety), CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)

Additional Information: See UL On-line Certification Directory at WWW.UL.COM for additional information.

Only those products bearing the UL Recognized Component Marks for the U.S. and Canada should be considered as being covered by UL's Recognition and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements.

The UL Recognized Component Mark for the U.S. generally consists of the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory. As a supplementary means of identifying products that have been produced under UL's Component Recognition Program, UL's Recognized Component Mark: may be used in conjunction with the required Recognized Marks. The Recognized Component Mark is required when specified in the UL Directory preceding the recognitions or under "Markings" for the individual recognitions. The UL Recognized Component Mark for Canada consists of the UL Recognized Mark for Canada: and the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory.

Look for the UL Recognized Component Mark on the product

William R. Carney
Director, North American Certification Programs

Underwriters Laboratories Inc.

7. Technical Specification

7.1 Classification

Mark of Origin (Manufacturer)		Baaske Medical GmbH & Co. KG Lübbecke, Germany
Type Designation		MI 1005
Operating Mode		Continuous operation
Environmental conditions during operation	Temperature	-10°C to +85°C
	Relative air humidity	10% to 90% (not condensing!)
	Air pressure	700 hPa to 1060 hPa
Environmental conditions during Storage/Transport	Temperature	-25°C to +85°C
	Relative air humidity	10% to 95% (not condensing!)
	Air pressure	500 hPa bis 1060 hPa
Dimensions (L x B x H)		65 x 29 x 23 mm
Weight		~ 50 g
Classification	Protection Class	Not applicable
	Protection against water penetration	No protection
	Degree of protection of the user parts against electric shock	Not applicable
	Degree of protection against discharge from defibrillators	Not applicable
	Protection during use in the presence of combustible compounds of anaesthetics with air or with oxygen or laughing gas	No protection
Connection to the supply		Not applicable
Supply frequency		Not applicable
Power input		Not applicable
Pollution degree		2

7.2 Technical Data

MI 1005	
Max Isolation Voltage between Ethernet connectors	5kV AC (50/60Hz 1 Minute)
Connection sockets	2 x RJ45
Network specifications	IEEE 803.2ab 10/100/1000-BaseT, Twisted-Pair, auto-conf (completely transparent in ethernet network, no drivers required)
Material	UL94V-0 complying materials RoHs compliant
MTBF	0,21 x 10^8 (1 Fault in 21 000 000 hrs)
Product rating	Passive ethernet isolating device, insulation rating DI (250V AC / 300V DC) tested at 5kVAC

8. Delivery Contents

- **MI 1005**
- User Manual
- TP Network Cable CAT6 25 cm (optional)

Check the delivery contents and request any missing items from your retailer immediately.

9. Warranty Regulations

These Representations and Warranties are applicable to all end-customers (the “Customers” and each, individually, a “Customer”) purchasing products (the “Products”) manufactured by Baaske Medical GmbH & Co. KG (the “Company”).

9.1 Warranty and Limitations:

9.1.1 Company warrants solely to the original purchaser of the Products that for the Warranty Period (as defined below), the Products will be free from defects in materials and workmanship under normal use, and will conform to Company’s published specifications of the Products. Notwithstanding the foregoing, Company retains its right to deviate from its published specifications due to the latest innovations and improvements in function and design of the Products. The foregoing warranty is subject to the proper storage, operation, transportation and use of the Products, and does not include defects due to normal unauthorized repairs, wear and tear or deterioration, lightening, fire, excessive voltage, humidity and unsuitable software programs.

9.1.2 Upon delivery, Customer shall immediately inspect the Products for conformity and visible defects. Customer shall give Company written notice of any non-conformities or visible defects immediately, but in no event later than two (2) weeks following delivery, and return the Products to Company at Company’s expense. In the event of any apparent shipping and freight damages of the Products, Customer shall refer any claims to the shipping company.

9.1.3 Customer shall notify Company in writing of any other defects of the Products within two (2) weeks upon discovery, and the Company shall not be obligated to accept any warranty claims based upon later notices. Company’s sole obligation under the foregoing warranty is, at Company’s option, to repair or correct any such covered defect or to replace or exchange the Product. Any repaired, corrected, replaced or exchanged Products shall be subject to the warranty set forth in 1.1., following their repair, correction, replacement or exchange.

9.1.4 With respect to orders made to custom, any defects of the Products caused by Customer’s specifications are excluded from the warranty set forth in 1.1.

9.1.5 Company also makes no warranty that the Products manufactured under an order made to custom do not infringe the intellectual property or other proprietary rights of any third party and Customer is solely responsible for assuring that such Products do not so infringe.

9.1.6 The “Warranty Period” begins on the date on which the Products are being physically delivered to Customer’s site, and continues to be in effect for one (1) year.

9.1.7 Company does not authorize any person or party to assume or create for it any other obligation or liability in connection with the Products except as set forth herein.

9.1.8 All requests and notices under this Warranty shall be directed to:

Customers in the United States and Canada:

Baaske Medical Inc.
Attn. Mr. Andreas Baaske
765 Baywood Drive, Suite 325
USA 94954 Petaluma, CA

Phone: +1 (707) 766 0447
Fax: + 1 (866) 442 7381

E-Mail: sales@baaske-medical.com

Customers in Europe and all other Countries:

Baaske Medical GmbH & Co. KG
Attn. Mrs. Sabine Spoenemann
Bacmeisterstr. 3
32312 Lübbecke, Germany

Phone: +49 5741 236027 - 0
Fax.: +49 5741 236027 - 99

E-mail: sales@baaske-medical.de

9.1.9 THE WARRANTY SET FORTH IN SECTION 1.1 IS MADE IN LIEU OF ALL OTHER WARRANTIES (WHETHER EXPRESS OR IMPLIED), RIGHTS OR CONDITIONS, AND CUSTOMER ACKNOWLEDGES THAT EXCEPT FOR SUCH LIMITED WARRANTY, THE PRODUCTS ARE PROVIDED "AS IS." COMPANY SPECIFICALLY DISCLAIMS, WITHOUT LIMITATION, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, OF ANY KIND, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND THOSE WARRANTIES ARISING FROM A COURSE OF PERFORMANCE, A COURSE OF DEALING OR TRADE USAGE.

9.2 Limitation of Liability:

9.2.1 IN NO EVENT SHALL COMPANY BE LIABLE FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, REVENUE, GOODWILL OR USE, INCURRED BY CUSTOMER OR ANY THIRD PARTY, WHETHER IN AN ACTION IN CONTRACT, TORT, STRICT LIABILITY, OR IMPOSED BY STATUTE, OR OTHERWISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. COMPANY'S LIABILITY FOR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT SHALL IN NO EVENT EXCEED THE PURCHASE PRICE OF THE PRODUCTS. IT IS AGREED AND ACKNOWLEDGED THAT THE PROVISIONS OF THIS AGREEMENT ALLOCATE THE RISKS BETWEEN COMPANY AND CUSTOMER, THAT COMPANY'S PRICING REFLECTS THIS ALLOCATION OF RISK, AND BUT FOR THIS ALLOCATION AND LIMITATION OF LIABILITY, COMPANY WOULD NOT HAVE ENTERED INTO THIS AGREEMENT.

9.2.2 IN JURISDICTIONS THAT LIMIT THE SCOPE OF OR PRECLUDE LIMITATIONS OR EXCLUSION OF REMEDIES OR DAMAGES, OR OF LIABILITY, SUCH AS LIABILITY FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR DO NOT ALLOW IMPLIED WARRANTIES TO BE EXCLUDED, THE LIMITATION OR EXCLUSION OF WARRANTIES, REMEDIES, DAMAGES OR LIABILITY SET FORTH ABOVE ARE INTENDED TO APPLY TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW. CUSTOMER MAY ALSO HAVE OTHER RIGHTS THAT VARY BY STATE, COUNTRY OR OTHER JURISDICTION.

10. Manufacturer Contact

For queries and problems please contact:

Manufacturer:
Baaske Medical GmbH & Co. KG
Bacmeisterstr. 3
32312 Lübbecke
Germany

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